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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,991	09/09/2003	Ridwan Shabsigh	0575/58075-Z/JPW/AJM/HA	4213

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John P. White
Cooper & Dunham LLP
1185 Avenue of the Americas
New York, NY 10036

EXAMINER	
KELLY, ROBERT M	

ART UNIT	PAPER NUMBER
1633	

MAIL DATE	DELIVERY MODE
06/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/658,991	SHABSIGH, RIDWAN	
	Examiner	Art Unit	
	Robert M. Kelly	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9,10 and 12-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9,10 and 12-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/24/07 has been entered.

Claims 12-21 are newly added.

Claims 9, 10, and 12-21 are presently pending and considered.

Claim Rejections - 35 USC § 112 – new matter

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 14-17 encompass a generic method of increasing VEGF levels in the penis. The specification and claims as filed do not teach or suggest anywhere such a generic method, but

only increasing the levels of VEGF in the penis as a mechanism for treating erectile dysfunction or increasing/maintaining blood supply (e.g., SPECIFICATION, pp. 5-6).

Moreover, the Art fails to demonstrate any generic method of increasing the amount of VEGF in the penis, other than as a mechanism for a method of treating erectile dysfunction (e.g., prosecution history).

Hence, at the time of invention, the Artisan would not have understood Applicant to have been in possession of a generic method of increasing VEGF levels in the penis.

Response to Argument – new matter

Applicant's argument of 4/24/07 has been fully considered but is not found persuasive.

Applicant argues that support is found on page 13, lines 17-24 and on page 12, lines 1-7 (p. 6, paragraph 1).

Such is not persuasive. The cited recitations only teach increasing or maintaining blood supply, and increasing or maintaining density of vascular structures, in the penis, which imply a mechanism of increased VEGF levels, however, such does not teach a generic method of increasing VEGF levels.

Claim Rejections - 35 USC § 112 - Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

While the previous rejections of Claims 9-10 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, are withdrawn;

Claims 9-10 and 12-21 are newly rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of increasing the amount of VEGF or increasing/maintaining blood supply, in a penis, wherein the subject is suffering from erectile dysfunction, comprising administration of a vector encoding VEGF into the corpus cavernosa, wherein the VEGF is expressed in the corpus cavernosa, thereby increasing or maintaining the blood supply in the corpus cavernosa, does not reasonably provide enablement for animals not suffering from erectile dysfunction or for transformation of any suitable cell, for reasons of record, as modified below. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Applicant's claims encompass treating normal as well as patients with erectile dysfunction, by transforming any "suitable cell", which is defined by the Specification to be any cell which can express VEGF and thereby increase or maintain the blood supply in the subject's penis (paragraph 0054), and at a minimum includes the corpus cavernosa and corpus spungiosum, but is not limited to such (paragraph 0004). Further, the claims do not require the expression of VEGF transgene, but only permissive conditions in the cell for expression of such. The purpose given throughout the specification for doing so is to treat erectile dysfunction, and hence, these claims must be enabled for treatment of erectile dysfunction.

The nature of the invention demonstrates that the art generally believed that new inventions in the field of gene therapy are not enabled, absent proof otherwise (e.g., Official Action of 1/13/06, pp. 9-10).

With regard to the prior art, such demonstrates conflicting results. Ming-Chan, et al, (2002) J. Urol., 167: 761-67 and Rogers, et al. (2003) Int. J. Impot. Res., 15: 26-37 teach that protein and gene therapy with VEGF administered to the corpus cavernosa, treat erectile dysfunction in rat penises. However, Burchardt (2005) J. Urol., 66: 665-70, provides conflicting results, in which VEGF or VEGF by way of gene therapy, provides no clinically useful increase in the blood supply, etc. Burchardt reviews the other two articles and concludes that the reason most likely to account for the differences is that Burchardt's methods involve the use of otherwise-normal rat penises, while the Ming-Chan and Rogers use models in which arterial ligations occurred, thereby lowering the normal blood flow (e.g., p. 669, paragraph 1).

Hence, the Artisan would not reasonably predict that such methods would work in otherwise-normal patients, but only those patients with erectile dysfunction.

With regard to the cells suitable for transformation, Bivalacqua, et al. (2001) J. Andrology, 22(2): 183-190, provides a review of the potential of gene therapy to effect treatment of erectile dysfunction . Bivalacqua makes clear that the corpora cavernosa is filled with vascularized sinuses, which fill with blood to cause the erection, and hence, it is therefore clear that these sinuses of the corpus cavernosa could theoretically benefit from increased vascularization (e.g., p. 184, col. 1, paragraph 2). However, the other portions of the penis, e.g., the corpus spongiosum, do not have any structure that would appear to benefit from increased vascularization (p. 183, col. 2, paragraph 2). Hence, the Artisan would recognize that, whatever the case, the tissue that would require vascularization is the corpus cavernosa, and would not reasonably predict that any other tissue could be treated.

With regard to the expression of VEGF, such must necessarily be expressed, as nothing in Applicant's specification and/or the Art demonstrates that the nucleic acid alone is required to provide therapeutic effect, and the only evidence is that the VEGF protein itself provides the effect (e.g., U.S. Patent No. 6,706,682, to Shabsigh).

Applicant's specification does not provide any more guidance or direction to reasonably predict more than is shown in the Art, and further, the Examples are limited to findings of which VEGF isoforms are present in the penis.

Hence, the Artisan would have to experiment to determine those VEGF transgenes which could be delivered to affect therapy in normal tissues, as well as affect therapy without expression and as well as determine those tissues to which it could be delivered, expressed, and have a therapeutic effect, as the Art indicates that normal penile tissues would not respond to VEGF therapy and further indicates that only the corpus cavernosa would have any beneficial affect. Such is considered undue, as it would amount to inventing the breadth of Applicant's invention for Applicant.

Therefore, these claims are only enabled for such breadth as provided in the initial paragraphs of this rejection.

Response to Argument – Enablement

Applicant's argument of 4/24/07 has been fully considered but is not found persuasive.

Applicant argues that with their demonstration of VEGF isoforms that are expressed in the penis, and their aversions throughout the specification of how to affect the method, such enables all the methods (pp. 7-8).

Such is not persuasive. The prior art demonstrates that normal penises are not responsive to VEGF treatment to increase any blood flow or have any affect on erectile dysfunction, as shown above.

Applicant reviews the art cited above, and concludes that the Art demonstrates successes, and that Burchardt is distinguished in using normal tissue, and that therefore, because they are not treating normal tissue, the Art enables the invention (pp. 8-9).

Such is not persuasive. Applicant's claims encompass treating normal tissues as well as those with erectile dysfunction. Hence, the invention is not enabled for its fully claimed scope.

Claims Free of the Prior Art

The claims remain free of the prior art of record.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Kelly, Art Unit 1633, whose telephone number is (571) 272-0729. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert M. Kelly, Ph.D.
Examiner, USPTO, AU 1633
Patents Hoteling Program
Mailbox 2C70, Remsen Building
(571) 272-0729